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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/763,632 | 01/23/2004 | James R. Lawter | ORA5002USACNT1 (J&JO-103U | 7747 |

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| EXAMINER | |
|---|---|
| BUMGARNER, MELBA N | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3732 | |

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/763,632 | LAWTER ET AL. | |
| | Examiner | Art Unit | |
| | Melba Bumgarner | 3732 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-41,47 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41,47 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-41, 47, and 48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 6,682,348. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the claims of the application and the claims of the patent lies in the fact that the patented claims include more elements and are thus more specific. The invention of the claims of the patent is in effect a species of the generic invention of the claims of the application, thus the claims of the application are not patentably distinct from the patented claims.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Martin (6,083,002). Martin discloses an apparatus 10 for dispensing material comprising a barrel 12 including a body portion and a tube portion, the tube portion extending from the body portion and including a tip 20 configured for being deformed to at least one different cross-sectional geometry (column 4 line 47); and a plunger 22, at least a portion of the plunger slideably housed within the barrel.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-21, 28-34, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brizzolara et al. (5,236,355) in view of Martin. Brizzolara et al. disclose an apparatus 2 for dispensing material comprising a barrel 10 including a body portion and a tube portion, the tube portion extending from the body portion and including a tip 7; and a plunger 4, at least a portion of the plunger slideably housed within the barrel and a quantity of dry particles 9, at least a portion of the dry particles within the tip; however, they do not show a tip configured for being deformed. Martin teaches an apparatus including a tip 20 configured for being deformed to at least one different cross-sectional geometry (column 4 line 47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Brizzolara et al. to have the tip of Martin to be able to place the tip at a particular location to

dispense the composition in view of Martin. Brizzolara et al. show the dry particles comprising at least one therapeutic agent of tetracycline, doxycycline, or minocycline (column 8 line 41). The dry particles comprise an effective amount of the therapeutic agent, the agent dispersed in a dry matrix comprising biocompatible and biodegradable polymer and the particles have a diameter of about 0.1 to 1000 microns (column 5 line 56). Brizzolara et al. show the therapeutic agent comprising from about 0.00001 to about 50 parts by weight per 100 parts by weight of the particles. Brizzolara et al. show the polymer comprising the limitations as claimed (column 7 line 52). Brizzolara et al. show the polymer becomes tacky upon contact with water (column 8 line 67). Brizzolara et al. show the barrel and plunger comprises olefin homopolymer of polypropylene (column 11 line 33). The agent includes minocycline hydrochloride (column 11 line 43). Brizzolara et al. show a removable closure 8. Brizzolara et al. show the apparatus enclosed in an aluminum-laminate pouch (column 11 line 13), sterilizable package, and barrel and plunger formed with radiation sterilizable materials (column 11 line 49). It is would have been an obvious matter of choice to one of ordinary skill in the art as to a known component being resealable. It would have been obvious as to the change in configuration to be circular and oval.

***Allowable Subject Matter***

7. Claims 22-27 and 36-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Any inquiry concerning this communication from the examiner should be directed to Melba Bumgarner whose telephone number is 571-272-4709. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melba Bumgarner

Melba Bumgarner
Primary Examiner